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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,638

12/22/2006

Barton Haynes

1579-1093

4199

23117 7590 11/30/2009
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EXAMINER

PARKIN, JEFFREY S

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

11/30/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/572,638	Applicant(s) HAYNES ET AL.	
	Examiner Jeffrey S. Parkin	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 116-134 is/are pending in the application.
- 4a) Of the above claim(s) 116-118 and 120-126 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 127-134 is/are allowed.
- 6) ☒ Claim(s) 119 is/are rejected.
- 7) ☒ Claim(s) 119 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>03/17/2006; 10/07/2008</u> . | 6) <input type="checkbox"/> Other: _____ |

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Detailed Office Action

Status of the Claims

Applicant's election with traverse of Group II (a nucleotide sequence corresponding to SEQ ID NO.: 37) in the reply filed on 23 March, 2009, is acknowledged. Applicants traverse and submit it would not constitute an undue burden to examine all of the claimed sequences concomitantly. It was further argued that a national stage application was considered to have unit of invention if the claims are drawn to a product and process of use. These arguments are not found persuasive for the reasons of record previously set forth and as further elaborated herein. First, contrary to Applicants' assertion, each of the identified sequences would necessitate a separate search by the Scientific and Technical Information Center (STIC). Applicants are reminded that the United States Patent and Trademark Office (Office) published an Official Gazette notice in November of 1996 providing a partial waiver of the requirements for restriction pursuant to 37 C.F.R. § 1.141 *et seq.* and for unity of invention determinations pursuant to 37 C.F.R. § 1.475 *et seq.* See Examination of Patent Applications Containing Nucleotide Sequences, 1192 Off. Gaz. Pat. Office 68 (Nov. 19, 1996) (1996 Notice). The 1996 Notice permitted examination of a reasonable number, normally up to ten, independent and distinct molecules described by their nucleotide sequence in a single patent application. The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in the complexity of applications filed, the types of inventions claimed and the state of the prior art in this technology since that time.

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Because of these changes, the search and examination of up to ten molecules described by their nucleotide sequence often consumes a disproportionate amount of Office resources over that expended in 1996. Consequently, with this Notice the Office rescinds the partial waiver of 37 C.F.R. § 1.141 *et seq.* for restriction practice in national applications filed under 35 U.S.C. § 111(a), and 37 C.F.R. § 1.475 *et seq.* for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. § 371. This Notice is effective immediately and is applicable to all pending applications. Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances. Second, Applicants are reminded that if multiple products, processes of manufacture, or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto, will be considered as the main invention in the claims (refer to PCT Article 17(3)(a) and § 1.476(c)). However, the elected sequence was not first mentioned in the claims. Moreover, each of the identified groups and sequences lacks unity of invention because of their divergent subject matter. Accordingly the requirement is still deemed proper and is therefore made **FINAL**. The Examiner would consider rejoining a single method of use claim and method of manufacture if SEQ ID NO.: 37 is free of the prior art. The Examiner would also consider examining more than one sequence in a future application if Applicants can demonstrate that the claimed sequences share a closely related structure. Claims 119 and 127-134 appear to read on the elected invention. Claims 116-

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118 and 120-126 are withdrawn from further consideration pursuant to 37 C.F.R. § 1.142(b), as being drawn to a nonelected invention. Claims 119 and 127-134 appear to read on the elected invention.

37 C.F.R. § 1.98

The information disclosure statements filed 17 March, 2006, and 07 October, 2008, have been placed in the application file and the information referred to therein has been considered.

Claims Objections

Claim 119 is objected to because it appears to depend from non-elected subject matter and also incorporate non-elected subject matter. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 119 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be

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protected by the patent grant. The claim depends from a number of non-elected claims. Moreover, it is not readily manifest which limitations are encompassed by the claim. Appropriate correction is required. It is suggested that Applicants rewrite the claim in an independent manner (e.g., An isolated nucleic acid encoding a consensus HIV Env wherein said nucleic acid comprises SEQ ID NO.: 37).

Allowable Subject Matter

Claims 127-134 appear to be free of the prior art of record and are allowable.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Larry R. Helms, can be reached at (571) 272-0832. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Applicants are reminded that the United States Patent and Trademark Office (Office) requires most patent related correspondence to be: a) faxed to the Central FAX number (571-273-8300) (updated as of July 15, 2005), b) hand carried or delivered to the Customer Service Window (now located at the Randolph Building, 401 Dulany Street, Alexandria, VA 22314), c) mailed to the mailing address set forth in 37 C.F.R. § 1.1 (e.g., P.O. Box 1450, Alexandria, VA 22313-1450), or d) transmitted to the Office using the Office's Electronic Filing System. This notice replaces all prior Office notices specifying a specific fax number or hand carry address for certain patent related correspondence. For further information refer to the Updated Notice of Centralized Delivery and Facsimile Transmission Policy for Patent Related Correspondence, and

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Exceptions Thereto, 1292 Off. Gaz. Pat. Office 186 (March 29, 2005).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

/Jeffrey S. Parkin/
Primary Examiner, Art Unit 1648

23 November, 2009